REMARKS

This document is filed in reply to the final office action dated January 28, 2010 ("Office Action"). Applicants have amended claim 3 to more clearly set forth the claimed invention. No new matter has been introduced. Claims 1 and 3-23 are pending. Among them, claims 12-19 have been withdrawn for covering a non-elected invention; claims 1, 3-11, and 19-23 are under examination.

Applicants have filed herewith a Request for Continued Examination and request that the above-mentioned amendment be entered and this application reviewed in view of the following remarks.

35 U.S.C. § 103 Rejections of Claims 1, 3-4, 7, 9-11, and 20-23

Claims 1, 3-4, 7, 9-11, and 20-23 were rejected for obviousness over US Patent No. 5128048 to Stewart *et al.* ("Stewart") in view of US Patent No. 5258127 to Gsell *et al.* ("Gsell"). See the Office Action, page 2, item 3. Applicants respectfully traverse and will discuss independent claim 1 first.

Claim 1 is drawn to a device for separating blood into blood components. The device includes, among others, a collecting container for receiving whole blood; a first satellite container connected to the collecting container through a leukocyte filter for receiving from the collecting container a leukocyte depleted first blood component; and a second satellite container connected with the collecting container for receiving from the collecting container a leukocyte depleted second blood component. The containers and filter are so connected that, once a whole blood (WB) sample is processed by the device, (1) the first satellite container receives from the collecting container a leukocyte depleted platelet rich plasma component (PRP) and (2) the second satellite container receives from collecting container a leukocyte depleted packed red cells component (PRC).

The Examiner rejected this claim on two grounds. Applicants respectfully traverse each of them below.

I

The preamble of claim 1 recites a "device for separating blood into blood components" (such as PRP and PRC). It is the Examiner's position that "[m]aterials such

blood, PRP, PRC, [and] WB ... [are] not given patentable weight in the [claim]." See the Office Action, page 3, lines 2-4.

Applicants disagree and would like to point out that the Examiner's position is inconsistent with the guidelines provided in the MPEP. Indeed,

> The determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case ... *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002). ...
>
> A claim preamble has the import that the claim as a whole suggests for it." *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999).
>
> Any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. See, e.g., *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989) (The determination of whether preamble recitations are structural limitations can be resolved only on review of the entirety of the application "to gain an understanding of what the inventors actually invented and intended to encompass by the claim.")

See MPEP 2111.02 (emphases added).

Here, the device of claim 1 is defined as containing a collecting container for receiving **whole blood,** various containers for receiving "**leukocyte** depleted" **blood components**, and a filter allowing "**platelets** to pass therethrough" (emphasis added). Clearly, the preamble is not merely a statement of effect that *may or may not be desired or appreciated*. Instead, "when read in the context of the entire claim" and "on review of the entirety of the application," the preamble of claim 1 "is 'necessary to give life, meaning, and vitality' to the claim." It follows that "the claim preamble should be construed as if in the balance of the claim" and "terminology [such as "blood" and "blood components," e.g., PRP, PRC] that limits the structure of the claimed invention must be treated as a claim limitation." Accordingly, the Examiner cannot ignore those

"materials" such as "blood," "PRP," "PRC," and "WB," when evaluating the patentability of the device of claim 1.

Thus, the Examiner's this ground for rejection is untenable.

II

As mentioned above, the device of claim 1 includes a number of containers and a leukocyte filter. The Examiner rejected claim 1, asserting that "[c]laim 1 essentially differs from the device of Stewart ... in reciting a leukocyte filter being configured to filter leukocytes and to allow platelets to pass therethrough." See the Office Action, page 3, lines 11-12. Citing Gsell, the secondary reference, the Examiner asserted that Gsell described a filter and would rectify the defect of Stewart. As such, the Examiner concluded that that a person of ordinary skill in the art would replace the leukocyte filter of Stewart with the Gsell filter for the "beneficial removal of leukocytes from PRP prior to platelet storage." See the Office Action, page 3, lines 20-23. Applicants disagree for the following reasons.

II-a

Stewart strongly dissuades a skilled person from seeking alternative leukocyte filters, especially prior art filters, due to various technical disadvantages attributed to these filters, such as requiring extra steps (like the Gsell filter) which can complicate the filtration process and increase processing times. See column 2, lines 8-22. In this connection, Applicants note that Gsell has a priority date earlier than that of Stewart. Therefore the Gsell filter would be within the scope of the prior art filter from which Stewart discouraged a skilled person.

Thus, to the extent that Stewart strongly dissuades a skilled person from seeking alternative leukocyte filters, especially prior art filters, it teaches away a skilled person from using the Gsell filter in the manner asserted by the Examiner.

II-b

Even if a skilled person would have used the Gsell filter, which Applicants do not concede, the Gsell filter is not sufficient to remedy the deficiencies of Stewart when

considering the features required by claim 1 as the blood collection and separation device configurations differ in several meaningful respects.

First, as mentioned above, claim 1 requires a first satellite container that is used for the collection of **platelet rich plasma** (PRP) received from the collection container *via* the leukocyte filter configured to allow **platelets** to **pass through the filter**. For this purpose, valve means are operated in such way that **fluid flow through by-pass tubing** is **excluded** (see claim 1, and page 7, paragraph 4). Contrary to claim 1, Stewart teaches that PRP is received from the collecting container ***via* the by-pass tubes**, thereby **circumventing the leukocyte filter entirely** (see Stewart, col. 5, lines 43-46, and col. 6, lines 14-18). Further, Stewart even teaches that handling of the **platelet** rich components (i.e. the PRP) should **avoid** the **leukocyte filter** altogether (see column 7, lines 34-41). In view of these teachings, the skilled artisan could **only** conclude that platelet-containing blood components must not contact or pass through the leukocyte filter.

Therefore, the skilled artisan would not arrive at the device of claim 1, which specifically purifies PRP from leukocytes by allowing the platelets to directly pass through the leukocyte filter. Gsell is completely silent regarding the use of bags and tubing connections during the blood purification process, and therefore does not rectify this deficiency of Stewart.

Second, also as mentioned above, the device of claim 1 requires "a leukocyte filter being configured to filter leukocytes and to allow platelets to pass therethrough so as to enable said first satellite container to receive from the said collecting container a leukocyte depleted platelet rich plasma component (PRP) and to enable said second satellite container to receive from said collecting container a leukocyte depleted packed red cells component (PRC)." Claim 1 further quires flow control means "such that ... whole blood (WB) is separable into the leukocyte depleted platelet rich plasma component (PRP) and the leukocyte depleted packed red cells component (PRC) **with a single leukocyte filter**" (emphasis added). Indeed, it is evident from the Specification that a device covered by the claim generates leukocyte-free PRC, PL, and PC using a **single filter** (see, e.g., page 8, paragraph 5).

In contrast, neither Stewart nor Gsell teaches or suggest that the **same leukocyte depletion filter** can **first** be used for the purification of **platelet rich plasma**, **and then** later for the purification of **red cells** from leukocytes. Nor is a teaching provided on how to avoid carrying over platelet rich plasma still contained in the filter after the first filtration step into the red blood cell fraction (as in the present application; see page 8, paragraph 2). Clearly, Stewart and Gsell fail to teach or suggest this device arrangement.

For the reasons set forth above, Applicants submit that independent claim 1 is non-obvious over Stewart in view of Gsell. The Examiner rejected independent claim 21 on the same grounds. For one or more of the reasons set forth above, claim 21 is patentable over Stewart in view of Gsell. So are claims 3-4, 7, 9-11, and 22-23, each of which depends from claim 1 or 21 directly or indirectly.

For a complete record, Applicants now address claim 3. Claim 3, dependent from claim 1, specifies that the above-mentioned second satellite container includes a blood additive. According to the Examiner, Stewart teaches (at FIG. 2) a second satellite container containing a blood additive "A." See the Office Action, page 4, lines 1-2. On this ground, the Examiner rejected claim 3.

Applicants disagree. FIG. 2 in Stewart is a schematic view of the system depicted by FIG. 1, showing a blood ***transfer*** assembly attached to a blood ***processing*** assembly (see Stewart, column 3, lines 62-65). Stewart at FIG. 1 clearly shows that additive "A" is contained **in the primary bag** 16, which serves to receive whole blood from a donor (see also column 4, lines 54-58). Unlike bag 16 of Stewart, the second satellite container in claim 3, which includes a blood additive "A," serves to receive a leukocyte depleted packed red cells component (PRC). Thus, the Examiner's ground for rejecting claim 3 is untenable and claim 3 is patentable over Stewart in view of Gsell on this independent ground.

35 U.S.C. § 103 Rejections of claims 5, 6, and 20

Claims 5-6 and 20 were rejected over Stewart in view of Gsell and WO 03/063930 by Corbin *et al.* ("Corbin"). See the Office Action, page 7, item 4.

Claims 5-6 and 20 all depend from claim 1, which has been discussed above. Applicants submit that, like Gsell, Corbin dose not rectify the defects of Stewart. Thus, for the same reasons discussed above, claims 5-6 and 20 are not obvious over the three cited references.

35 U.S.C. § 103 Rejections of claim 8

The Examiner rejected claim 8 for obviousness over Stewart in view of Gsell and US Patent No. 7264068 to Bischof *et al.* ("Bischof"). See the Office Action, page 7, item 5. Applicants note that, like Gsell, Bischof dose not rectify the defects of Stewart. Thus, for the same reasons discussed above, claim 8 is patentable over Stewart in view of Gsell and Bischof.

In addition, claim 8, dependent from claims 1 and 4, requires a one-way valve, which is located in a by-pass conduit. This by-pass conduit allows fluid flow only from the second satellite container to the collecting container. See claims 4 and 8. That is, the one-way valve feature is used to prevent undesired flow between the collecting container and the second satellite container, thereby preventing contamination of filtrated PRC with unpurified starting product whole blood (see also the Specification, page 6, paragraph 5). In contrast, Bischof teaches use of a one-way valve for preventing flow from a pooling container to a transfer container, wherein the transfer container contains platelets **already purified** by centrifugation (see Bischof column 3, lines 32-37), and wherein the pooling container contains platelets derived from several donors (see Bischof column 7, lines 52-58). In view of these teachings, a skilled person would not arrive at the one-way valve located in the by-pass conduit as required in claim 8 by combining the three cited references in the manner asserted by the Examiner. Thus, claim 8 is patentable over Stewart in view of Gsell and Bischof.

CONCLUSION

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the

arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Please apply any other charges or credits to Deposit Account No. 50-4189, referencing Attorney Docket No. 7B901-004US1.

Respectfully submitted,

Date: 4-26-2010

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